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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,939	12/17/2004	Mohammad R Marzabadi	67440-A-PCT-US	2867
45821	7590	08/17/2006		
LUNDBECK RESEARCH USA, INC. ATTENTION: STEPHEN G. KALINCHAK, LEGAL 215 COLLEGE ROAD PARAMUS, NJ 07652			EXAMINER AULAKH, CHARANJIT	
			ART UNIT 1625	PAPER NUMBER

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

### Office Action Summary

Application No.

10/518,939

Applicant(s)

MARZABADI ET AL.

Examiner

Charanjit S. Aulakh

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1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29-33 is/are allowed.
- 6) ☒ Claim(s) 1-5, 21, 22 and 34-48 is/are rejected.
- 7) ☒ Claim(s) 6-20 and 23-28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/20/05, 7/11/06.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

1. Claims 1-48 are pending in the application.

#### ***Claim Objections***

2. Claims 3-7, 11-13, 15, 16 and 20-22 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in alternate only. See MPEP § 608.01(n).

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 37-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The following eight different factors (see Ex parte Foreman, 230 USPQ at 547; Wands, In re, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on at least four of the above mentioned eight different factors such as quantity of experimentation

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necessary, presence of working examples, the state of the prior art, unpredictability and the breadth of claims.

The instant specification teaches that the instant compounds are antagonists of MCH1 receptor as evidenced by binding data presented in table I ( see pages 101-107 ). The specification also provides guidance to test the effects of instant compounds in animal models of obesity (consumption of sweetened condensed milk), depression (forced swim test), anxiety (social interaction test) and urge incontinence (micturition reflex and DIRC model) on pages 113-120. However, there are no working examples present ( no data with even a single compound ) showing effectiveness of instant compounds in any one of these animal models. There is no teaching either in the specification or prior art regarding specific disorders which are solely mediated by MCH 1 receptors. There is no teaching either in the specification or prior art references provided showing efficacy of structurally closely related compounds in any known animal models of obesity, depression, anxiety or urge incontinence. There is lot of unpredictability whether these compounds will actually have efficacy or not in any one of these animal models of obesity, depression, anxiety or urge incontinence. The instant compounds of formula of claim 1 encompasses hundreds of thousands of compounds based on the values of variables R1, R2, R3, n, t and the spirocyclic ring system and therefore, in absence of such teachings, presence of working examples, unpredictability and state of the prior, it would require undue experimentation to demonstrate the efficacy of instant compounds in animal models of every known disorder which is mediated by MCH1 receptors

including depression, anxiety, obesity and urge incontinence and hence their utility for treating these disorders.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-5, 21, 22 and 34-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In independent claim 1, variables t and n are not legible in the structural formula.

In claims 2-5, 21 and 22, variable n is not legible in structural formulae.

In claims 37 and 38, the term ---disorder mediated by MCH1 receptor ---- is indefinite since specific disorders are not defined.

***Allowable Subject Matter***

7. Claims 6-20 and 23-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claims 29-33 are allowed.

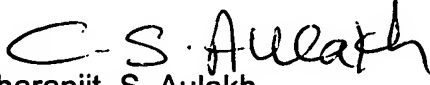
9. The instant compounds are allowable over the prior art since they are neither disclosed nor obvious over the prior art. In the art, Moriya ( US 2006/0106046, cited on applicants form 1449 ) discloses MCH1 receptor antagonists in tables 2-5 ( see pages 35-44 ) which do anticipate the instant compounds. However, this publication does not constitute a prior art reference since this publication, the corresponding PCT ( WO

04/069798 ) as well as the priority document ( JP 2003-032123 ) were all published after the effective filing date ( July 3, 2003 ) of the instant application.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on (571)272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Charanjit S. Aulakh  
Primary Examiner  
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